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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/798,440	03/12/2004	Tai Chih Kuo	KUOT3010/EM	5252
23364	7590	09/17/2004	EXAMINER	
BACON & THOMAS, PLLC 625 SLATERS LANE FOURTH FLOOR ALEXANDRIA, VA 22314			DESAI, ANAND U	
			ART UNIT	PAPER NUMBER
			1653	

DATE MAILED: 09/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/798,440	KUO ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Anand U Desai, Ph.D.	1653	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 12 March 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)             | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

## DETAILED ACTION

### *Priority*

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file. The priority date is November 21, 2003.

### *Specification*

2. The abstract of the disclosure is objected to because there is typographical error. There are two period punctuation marks on line 7 of the abstract. Correction is required. See MPEP § 608.01(b).
3. The disclosure is objected to because of the following informalities:
4. There is a typographical error on page 2, lines 22 and 23. The word appears to be "volume."
5. There is typographical error on page 2, line 25. The word appears to be "attach."
6. On page 5, line 6, there is a space missing between the comma and the word "glass."
7. On page 7, line 10, the word appears to be intended to be "research."
8. On page 8, line 11, the word "at" does not appear to be necessary.
9. On page 8, lines 27-28, the sentence appears to be, "The recombinant TSPN like domain modified with biotin was mixed with iron beads modified with streptavidin."
10. On page 8, line 29, the sentence appears to be "...iron beads were removed..."
11. The use of the trademark "TALON" has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Art Unit: 1653

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Appropriate correction is required.

### ***Claim Objections***

12. Claims 2, 12, 19 and 22 are objected to because of the following informalities:

13. In claims 2, and 12, the abbreviations of, GST and IDA, should be spelled out as glutathione S transferase, and iminodiacetic acid, respectively, at the first occurrence.

Alternatively, in claim 11 the abbreviation, IDA, can be placed next to the name.

14. In claim 19, the word, "imimidazole" is misspelled.

15. In claim 22, the word, "protien" is misspelled.

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 103***

16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

17. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out

Art Unit: 1653

the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

18. Claims 1-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Enomoto et al. in view of Cosma and Terpe.

Enomoto et al. disclose the construction of a series of vectors for the expression of epitope- and affinity-tagged fusion proteins in yeast and *E. coli*. The affinity tag is composed of six consecutive histidine residues that enables the facile purification of a fusion protein on metal columns (see p.782, Introduction). Enomoto et al. transformed both yeast and *E. coli* with a vector containing a gene for RLF2, which encodes for the large subunit of yeast chromatin assembly factor I (see p. 784, section on Functional Complementation from YGALSET Vector). The RLF2p fusion proteins expressed in *E. coli* or *S. cerevisiae* have been specifically enriched on commercially available nickel columns (Ni-NTA<sup>TM</sup>, QIAGEN) (see p. 786, First paragraph upper left hand corner). Enomoto et al. do not disclose the step of immobilizing the fusion protein.

Cosma discloses a method for detectably labeling with biotin a subset of a larger population of proteins comprising first (i) contacting the larger population of proteins with an affinity element, attached to a solid phase element, which selectively binds to the subset of proteins, under conditions which permit binding of the affinity element to the subset of proteins to occur; (ii) removing protein not bound to the solid phase element; and (iii) linking biotin to the subset of proteins bound to the solid phase element ("biotinylating") (see column 2, lines 44-53). Cosma also discloses elution of the biotinylated protein from an affinity column by ligand

Art Unit: 1653

or a competitive inhibitor of the ligand-ligand partner interaction, or maybe eluted by altering conditions such as ionic strength or pH of an elution buffer (see column 3, lines 55-60).

Terpe discloses the importance of immobilization of biologically active proteins for research and industry (see Conclusion section, last three sentences). Thus it would have been obvious to one of ordinary skill in the art at the time the invention was made to express a tagged protein according to the process of Enomoto et al., and recover the recombinant protein using a metal chelation column that binds the histidine tag. Although Enomoto et al. does not provide the last step of immobilizing a recombinant protein on a substrate as currently claimed, Terpe provides the state of knowledge in the art and the motivation to immobilize proteins to study functional domains of biologically active proteins once they are immobilized. Further, Cosma discloses the process of accomplishing this by labeling a tagged protein with biotin. It is well known in the art that biotin binds avidin. Therefore, it would have been obvious to the person having ordinary skill in the art to purify, modify, and immobilize recombinant tagged proteins using the molecular biological and chromatographic steps disclosed to study functional domains of biologically active proteins (current application, claims 1-22).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anand U Desai, Ph.D. whose telephone number is (571) 272-0947. The examiner can normally be reached on Monday - Friday 9:00 a.m. - 5:30 p.m..

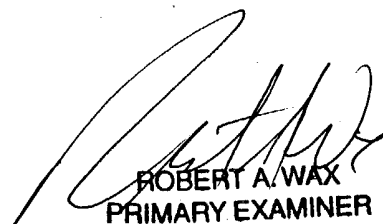
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber can be reached on (517) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 1653

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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September 3, 2004



ROBERT A. WAX  
PRIMARY EXAMINER